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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

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Certifier Sheese

Implantation or Injectable Dosage Form New Animal Drugs; Trenbolone Acetate

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) and an abbreviated supplemental new animal drug application (ANADA) filed by Intervet, Inc., and Ivy Laboratories, Division of Ivy Animal Health, Inc., respectively. The supplemental NADA and ANADA provide for the addition of statements to labeling of subcutaneous implants containing trenbolone acetate warning against the use of these products in calves to be processed for veal.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Eric S. Dubbin, Center for Veterinary Medicine (HFV-126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0232, e-mail: edubbin@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Intervet, Inc., 29160 Intervet Lane, P.O. Box 318, Millsboro, DE 19966, filed a supplement to NADA 138-612 for FINAPLIX-H (trenbolone acetate). Ivy Laboratories, Division of Ivy Animal Health, Inc., 8857 Bond St., Overland Park, KS 66214, filed a supplement to ANADA 200-224 for COMPONENT T-H and COMPONENT T-S (trenbolone acetate),
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COMPONENT T-H with TYLAN and COMPONENT T-S with TYLAN (trenbolone acetate with tylosin tartrate). The supplemental NADA and ANADA provide for the addition of statements to labeling warning against the use of these products in calves to be processed for veal. The supplemental applications are approved as of October 22, 2004, and the regulations are amended in 21 CFR 522.2476 to reflect the approval and a current format. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), summaries of safety and effectiveness data and information submitted to support approval of these applications may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that these actions are of a type that do not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 522

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

- 1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

- 2. Section 522.2476 is amended by removing paragraph (a); by redesignating paragraphs (b), (c), and (d) as paragraphs (a), (b), and (c); and by revising newly redesignated paragraphs (a)(1), (a)(2), (c)(1)(iii), and (c)(2)(iii) to read as follows:

§ 522.2476 Trenbolone acetate.

(a) * * *

(1) No. 021641 for use as in paragraph (c) of this section.

(2) No. 057926 for use as in paragraphs (c)(1)(i)(A), (c)(1)(ii), (c)(1)(iii), (c)(2)(i)(A), (c)(2)(ii), and (c)(2)(iii) of this section.

* * * * *

(c) * * *

(1) * * *

(iii) *Limitations.* Implant subcutaneously in ear only. Do not use in animals intended for subsequent breeding or in dairy animals. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(2) * * *

(iii) *Limitations.* Implant subcutaneously in ear only. Do not use in animals intended for subsequent breeding or in dairy animals. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been

established for this product in preruminating calves. Do not use in calves to be processed for veal.

Dated: November 18, 2004

November 18, 2004.

Steven D. Vaughn

Steven D. Vaughn,
Director,
Office of New Animal Drug Evaluation, Center for Veterinary Medicine.
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